

**EPA REGISTRATION NUMBER 70310-6 Vol. 1**

# Debug Aza MUP

## For Manufacturing Use Only

**ACCEPTED**

**01/13/2016**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 70310-6

**Active Ingredient:**

Azadirachtin\*..... 25.0%

**Other Ingredients**..... 75.0%

**Total**..... 100.0%

\*Derived from neem seeds 0.25 lbs (113 grams) of Active  
Ingredient per pound of product

**KEEP OUT OF REACH OF CHILDREN**

### WARNING

**See below for additional precautionary statements.**

Net Contents: (10lbs, 25lbs, 100lbs, 220lbs)

EPA Reg. No. 70310-A      EPA Est. No. 70310-IND-002

**Manufactured For**

Agro Logistic Systems, Inc.  
P.O. Box 5799, Diamond Bar, CA 91765, U.S.A.  
Website: [www.agrologistic.com](http://www.agrologistic.com)  
TEL: (714) 990-9220  
FAX: (714) 990-9222 e-mail:  
[info@agrologistic.com](mailto:info@agrologistic.com)

FIRST AID	
<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Immediately rinse skin with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to mouth, if possible.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If in Eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>



Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 AM to 4:30 PM Pacific Time (NPIC Web Site: [www.npic.orst.edu](http://www.npic.orst.edu)).

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For manufacturing use only. For formulation into insecticides, miticides, fungicides, and nematocides, for the following general use patterns: Terrestrial food crop and nonfood crop, greenhouse food crop and nonfood crop, residential outdoor/indoor.

This product may be used to formulate products for any additional use(s) not listed on this label if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

## **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING**

Harmful if absorbed through skin or if inhaled. Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear (goggles, face shield, or safety glasses). Avoid breathing spray. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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## **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.



## **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in a cool, dry area. Always store pesticides in the original container. Store away from food and pet food. Do not refrigerate.

**Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused <sup>1</sup> dispose of in the same manner. Do not burn unless allowed by state and local ordinances.

## **WARRANTY STATEMENT**

AGRO LOGISTIC SYSTEMS, INC. warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with the directions under normal use conditions. To the extent permitted by law, AGRO LOGISTIC SYSTEMS, INC. disclaims any liability for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. It is the manufacture's intention that the buyer assumes risk of use, storage, or handling of this material not in strict accordance with directions given herein. To the extent consistent with applicable law, Agro Logistic Systems, Inc. makes no warranties of merchantability or fitness for a particular purpose nor any other express or implied warranty except as stated above.



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

**WASHINGTON, D.C. 20460**

**OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION**

**MEMORANDUM**

**DATE:** December 17, 2015

**SUBJECT:** Science Review of Section B672 Registration for Debug AZA MUP (EPA Symbol #: 70310-A), Containing 0.7% of Azadirachtin and 15.04% of Neem Oil as its active ingredients (A.Is.). Review of CSF, Label, Product Chemistry and Toxicity

**Decision Number:** 502429  
**DP Number:** 428935  
**EPA File Symbol Number:** 70310-A  
**Chemical Class:** Biochemical  
**PC Code:** 121701

**FROM:** Shenell L.T. Bolden, Biologist  
BPB/BPPD (7511P)

Handwritten signature of Shenell L.T. Bolden in blue ink.

**THRU:** Russell Jones, Ph.D, Senior Scientist  
BPB/BPPD (7511P)

Handwritten signature of Russell Jones in blue ink.

**TO:** Gina Burnett, Acting Senior Regulatory Action Leader  
BPB/BPPD (7511P)

**Action Requested:**

On behalf of AgroLogistics, John Fournier has submitted an application for a Section B672 registration for the manufacturing use product, Debug AZA MUP (EPA Symbol #: 70310-A), containing 25% of Neem Oil as its active ingredient (A.I.). This product is intended for formulation into insecticides, miticides, fungicides, and nematicides, for the following general use patterns: Terrestrial food crop and nonfood crop, greenhouse food crop and nonfood crop, residential outdoor/indoor. This product may be used to formulate products for any additional use(s) not listed on this label if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).



In support of this registration, the registrant has submitted a label, basic Confidential Statements of Formula (CSF), dated 08/19/15, product chemistry (MRID: 495867-01 to 02) and data and information submission for acute toxicity studies (MRID 495867-03). BPPD has reviewed and evaluated the submissions for the registration of the manufacturing use product, Debug AZA MUP (EPA Symbol #: 70310-A). The decisions are made to reflect the current OCSPP's policies.

#### Conclusions:

1. The Confidential Statement of Formula (CSF) is **ACCEPTABLE**.
2. Product Chemistry is **ACCEPTABLE**.
3. Acute Toxicity is **ACCEPTABLE**.
4. Non-Target is **ACCEPTABLE**.

#### STUDY SUMMARIES

##### Confidential Statements of Formula (CSF)

A basic Confidential Statement of Formula (CSF), dated 08/19/15, product chemistry for the manufacturing use product, DEBUG AZA MUP (EPA Symbol No.: 70310-A) has been submitted. The product contains 25% of Azadirachtin as its active ingredient.

The nominal concentrations and certified limits are listed in Table 1 for the active ingredients in the manufacturing use product DEBUG AZA MUP.

TABLE 1. Nominal CSF concentrations and certified limits for Azadirachtin 25% <sup>a</sup>					
Ingredients (CAS number)	PC Code	Purpose	Concentration (% by weight)		
			Nominal	Upper	Lower
Active Ingredient					
Azadirachtin (25.0 %) (11141-17-6)	121701	Active Ingredient	25.0% (250.00)	25.75% (257.50)	24.25% (242.50)

<sup>a</sup>Data from CSF 08/19/15

##### Physical and Chemical Characteristics

The product chemistry data for the manufacturing use product, DEBUG AZA MUP (EPA Symbol No.: 70310-A) containing Azadirachtin 25% as its active ingredient is completed. There are no reported impurities of toxicological concern. The Series 830 physical and chemical properties are given in Table 2.



**TABLE 2. Physical and Chemical Properties for DEBUG AZA MUP\***

Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Light yellow powder, garlic nutty	-
830.6303 Physical State		
830.6304 Odor		
830.6315 Flammability	> 250°C (>482°F)	-
830.6317 Storage Stability	2 years	-
830.6319 Miscibility	Soluble in water.	-
830.6320 Corrosion Characteristics	Not corrosive to its packaging (HDPE) containers or metals	-
830.7000 pH	3.53	-
830.7300 Density/Relative Density/Bulk Density	0.49 no units given	-

\*Data from MRID 495867-02

### Product Identity and Composition

Active Ingredient:

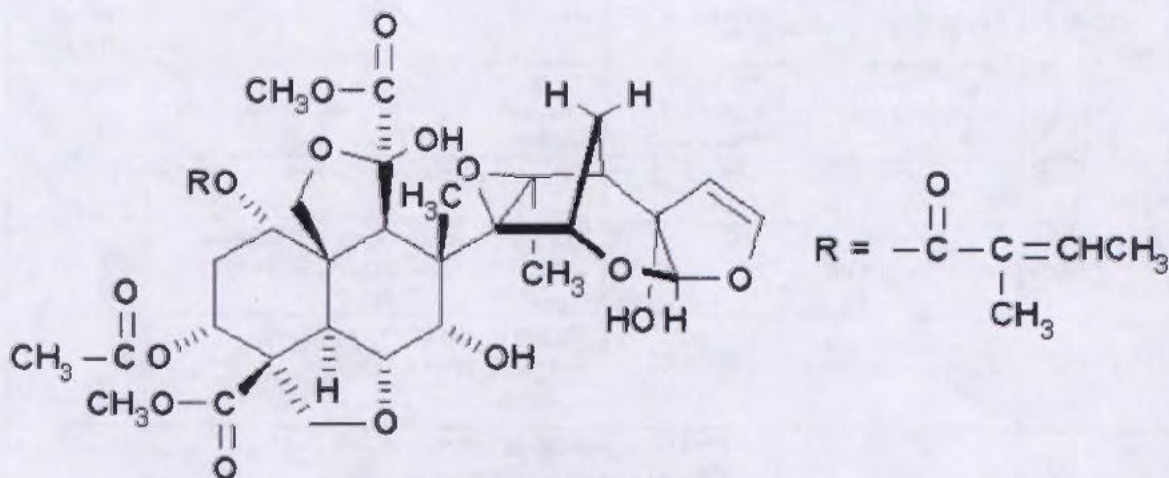
Common name: Cold Processed Neem Oil

Chemical name: Azadirachtin

CAS: 11141-17-6

Molecular Formula: C<sub>35</sub>H<sub>44</sub>O<sub>1</sub>

Molecular Weight: 720.21



**Structure of Azadirachtin**



Description of Starting Materials – SEE CONFIDENTIAL APPENDIX

Description of Production and Formulation Process (from email dated 12/08/2015 from John Fournier to Gina Burnett – SEE CONFIDENTIAL APPENDIX)

Discussion of the Formation of Impurities (from email dated 12/08/2015 from John Fournier to Gina Burnett – SEE CONFIDENTIAL APPENDIX)

**Tier I Acute Toxicity (OPPTS 870.1100 - 1300 & 870.2400 – 2600)**

No acute toxicity studies have submitted for the manufacturing use product, DEBUG AZA MUP (EPA Symbol No.: 70310-A). The registrant proposes to use acute toxicity studies for the TGAI product, Azadirachtin (EPA Reg. No.: 70310-4) to support the registration of the manufacturing use product, DEBUG AZA MUP (EPA Symbol No.: 70310-A).

The information of acute toxicities (MRIDs: 49886703 using the TGAI product, Azadirachtin (EPA Reg. No.: 70310-4) as test materials are summarized in Table 3.

<b>TABLE 3 Acute Toxicity Profile – Azadirachtin</b>				
<b>Guideline No.</b>	<b>Study Type</b>	<b>MRID(s)</b>	<b>Results</b>	<b>Toxicity Category</b>
870.1100	Acute oral [rat]	425383-02 446448-10	The oral LD <sub>50</sub> for rats was greater than 5000 mg/kg.	IV
870.1200	Acute dermal [rat]	425383-03 446448-11	LD <sub>50</sub> = > 2000mg/kg for rats	III
870.1300	Acute inhalation [rat]	446448-12	The single exposure acute inhalation LC <sub>50</sub> of the test substance is greater than 0.72 mg/L in rats.	IV
870.2400	Acute eye irritation [rabbit]	425383-04 446448-13	Causes moderate eye irritation following acute exposure	II
870.2500	Acute dermal irritation [rabbit]	425383-03 446448-11 425383-05 446448-14	Slightly irritating	IV
870.2600	Skin sensitization [guinea pig]	425383-06 446448-21	The test substance is not considered to be a contact sensitizer.	IV



Conclusions:


The acute toxicity studies for Azadirachtin are **ACCEPTABLE** to support the registration of the manufacturing use product, DEBUG AZA MUP (EPA Symbol No.: 70310-A). Acute toxicities for the manufacturing use product, DEBUG AZA MUP should be classified as Toxicity Category IV for acute oral toxicity, acute dermal irritation, skin sensitization and for acute inhalation; Toxicity Category III acute dermal; and Toxicity Category II for acute eye irritation. The test substance is not considered to be a contact sensitizer.

Non-Target Organisms

The studies for Non-Target Organisms are not required for this registration.

**\*\*Confidential Appendix\*\***

\*Manufacturing process information may be entitled to confidential treatment\*









UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 20, 2016

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

AGRO LOGISTIC SYSTEMS, INC.  
PO.BOX : 5799  
DIAMOND BAR, CA 91765

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 04-DEC-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

49789201

\* A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40CFR160 is required for all studies (except rangefinding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

\* End-use product-specific product chemistry data covered by guideline series 61, 62, and 63 can be combined and submitted as a single study. If you wish to claim confidentiality for material in series 61 or 62 under FIFRA section 10(d)(1), be sure to remove it from the body of the combined study, and place it in a Confidential Attachment. Assuming a Confidential Attachment is present, the study should be arranged like this: Page 1 of x Title Page  
Page 2 of x Statement of Data Confidentiality Claims (version 2) Page 3 of x  
The body of the study, including all non-confidential data, with cross references to the location in



the Confidential Attachment x of x of each passage claimed as confidential.  
 Page 1 of y Cover page of Confidential Attachment. 2 of y  
 Confidential data, with a page-specific cross reference at the beginning of each passage to the  
 location in the body of the study from y of y which it was removed.

\* You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

49789202

\* You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

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49789203

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**AGRO  
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.  
Ph: 714-990-9220, Fax: (714) 990-9222 [www.agrologistic.com](http://www.agrologistic.com)

49789200

Shyam K. Chari, President  
Agro Logistic Systems, Inc.  
P.O. Box 5799  
Diamond Bar, CA 91765  
Tel. (714) 990-9220; email: [shyam@agrologistic.com](mailto:shyam@agrologistic.com)

Gina Burnett, Regulatory Action Leader, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs, EPA  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

December 02, 2015

RE: **Application for New Product Registrations**  
**File Symbol 70310-A: Debug Aza MUP, PRIA Category B673**  
**File Symbol 70310-T: Debug Optimo, PRIA Category B670**  
**File Symbol 70310-I: Debug Tres, PRIA Category B670**

Dear Ms. Burnett:

Please refer to your email of December 02, 2015 for the above submissions.

You have identified the following remaining corrections-

1. Debug Aza MUP- EPA Symbol 70310- A : The manufacturing process schematic should describe the [REDACTED] as stated in the manufacturing process write-up.

Response: We have corrected the manufacturing process schematic to reflect the [REDACTED] as stated in the manufacturing write up. The complete Product Chemistry Group A, Part 2 of 2 is attached with the corrections.  
The Manufacturing Use Label is also attached as requested.

2. Debug Tres- EPA Symbol 70310-I: The manufacturing process schematic needs to be revised to be more clear. [REDACTED]

Response: We have corrected the schematic to clarify the process. [REDACTED]

In addition the ingredient amounts listed in the manufacturing process of the final product on this page is corrected to add up to 100%.

\*Manufacturing process information may be entitled to confidential treatment\*





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Ph: 714-990-9220, Fax: (714) 990-9222 [www.agrologistic.com](http://www.agrologistic.com)

3. Debug Optimo- EPA Symbol 70310-T: The manufacturing process schematic needs to be revised to be more clear. [REDACTED]

Response: We have corrected the schematic to clarify the process. [REDACTED]

In addition the ingredient amounts listed in the manufacturing process of the final product on this page is corrected to add up to 100%.

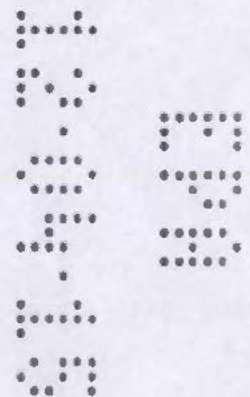
Also attached is the corrected Master Labels for Debug Tres (EPA Symbol 70310-I) and Debug Optimo (EPA Symbol 70310-T).

Respectfully,

Shyam K. Chari, President  
Agro Logistic Systems, Inc.  
P.O. Box 5799

Diamond Bar, CA 91765

Tel. (714) 990-9220; email: [shyam@agrologistic.com](mailto:shyam@agrologistic.com)



## TRANSMITTAL DOCUMENT

Date: 12/02/2015

Company:

AGRO LOGISTIC SYSTEMS, INC  
555 W. LAMBERT ROAD, UNIT-N  
BREA, CA 92821  
714-990-9220

Product Name/EPA Reg. #: Debug Aza MUP, Debug Optimo and Debug Tres (70310-A, 70310-T and 70310-I)

<u>MRID</u>	<u>Study No.</u>	<u>Study Title</u>
49789201	1	Group A Product chemistry for Debug Aza MUP
49789202	2	Group A Product chemistry for Debug Tres
49789203	3	Group A Product chemistry for Debug Optimo

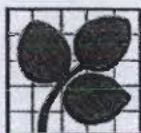


studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

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	y of y	which it was removed.



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49789200

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Gina Burnett, Regulatory Action Leader, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs, EPA  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

December 02, 2015

RE: **Application for New Product Registrations**  
**File Symbol 70310-A: Debug Aza MUP, PRIA Category B673**  
**File Symbol 70310-T: Debug Optimo, PRIA Category B670**  
**File Symbol 70310-I: Debug Tres, PRIA Category B670**

Dear Ms. Burnett:

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You have identified the following remaining corrections-

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Response: We have corrected the manufacturing process schematic to reflect the [REDACTED] as stated in the manufacturing write up. The complete Product Chemistry Group A, Part 2 of 2 is attached with the corrections.  
The Manufacturing Use Label is also attached as requested.

2. Debug Tres- EPA Symbol 70310-I: The manufacturing process schematic needs to be revised to be more clear. [REDACTED]

Response: We have corrected the schematic to clarify the process. [REDACTED]

In addition the ingredient amounts listed in the manufacturing process of the final product on this page is corrected to add up to 100%.

\*Manufacturing process information may be entitled to confidential treatment\*





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Ph: 714-990-9220, Fax: (714) 990-9222 [www.agrologistic.com](http://www.agrologistic.com)

3. Debug Optimo- EPA Symbol 70310-T: The manufacturing process schematic needs to be revised to be more clear. [REDACTED]

Response: We have corrected the schematic to clarify the process. [REDACTED]

In addition the ingredient amounts listed in the manufacturing process of the final product on this page is corrected to add up to 100%.

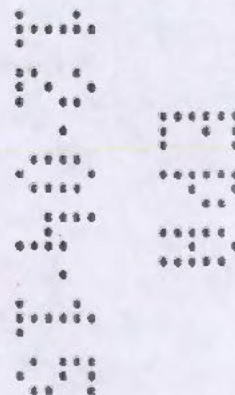
Also attached is the corrected Master Labels for Debug Tres (EPA Symbol 70310-I) and Debug Optimo (EPA Symbol 70310-T).

Respectfully,

Shyam K. Chari, President  
Agro Logistic Systems, Inc.  
P.O. Box 5799

Diamond Bar, CA 91765

Tel. (714) 990-9220; email: [shyam@agrologistic.com](mailto:shyam@agrologistic.com)



## TRANSMITTAL DOCUMENT

Date: 12/02/2015

Company:

AGRO LOGISTIC SYSTEMS, INC  
555 W. LAMBERT ROAD, UNIT-N  
BREA, CA 92821  
714-990-9220

Product Name/EPA Reg. #: Debug Aza MUP, Debug Optimo and Debug Tres (70310-A, 70310-T and 70310-I)

<u>MRID</u>	<u>Study No.</u>	<u>Study Title</u>
49789201	1	Group A Product chemistry for Debug Aza MUP
49789202	2	Group A Product chemistry for Debug Tres
49789203	3	Group A Product chemistry for Debug Optimo



# Rejected

# Study

( 0 1 )

ph

**CONFIDENTIAL ATTACHMENT: CONTAINS CONFIDENTIAL BUSINESS INFORMATION**

**STUDY TITLE**

Group A Product Chemistry for Debug Aza MUP

**DATA REQUIREMENTS**

Product Identity and Composition: OPPTS 880.1100

Description of Starting materials, Production and Formulation Process: OPPTS 880.1200

Discussion of Formation of Impurities: OPPTS 880.1400

Preliminary Analysis: OPPTS 830.1700

**PERFORMING FACILITY**

Agro Logistics Systems Inc.

P.O. Box 5799

Diamond Bar, CA 91765

**PROJECT IDENTIFICATION**

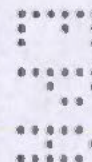
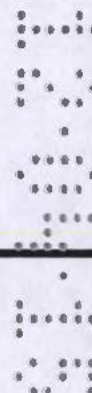
AGRO LOGISTIC 15-05

**DATE**

December 02, 2015

**PAGE 1 OF 11**

**Volume 2 of 2**



Pages 25-34 Manufacturing process information may be entitled to confidential treatment\*

\*Quality control process information may be entitled to confidential treatment\*

\*Inert ingredient information may be entitled to confidential treatment\*



# Debug Aza MUP

## For Manufacturing Use Only

**Active Ingredient:**

Azadirachtin\* ..... 25.0%

**Other Ingredients** ..... 75.0%

Total ..... 100.0%

- Derived from neem seeds 0.25 lbs (113 grams) of Active Ingredient per pound of product

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

See below for additional precautionary statements.

Net Contents: (10lbs, 25lbs, bulk)

EPA Reg. No. 70310-A      EPA Est. No. 70310-IND-002

**Manufactured For**

Agro Logistic Systems, Inc.

P.O. Box 5799, Diamond Bar, CA 91765, U.S.A.

Website: [www.agrologistic.com](http://www.agrologistic.com)

TEL: (714) 990-9220

FAX: (714) 990-9222 e-mail:

[info@agrologistic.com](mailto:info@agrologistic.com)

#### FIRST AID

<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Immediately rinse skin with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<p>Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 AM to 4:30 PM Pacific Time (NPIC Web Site: <a href="http://www.npic.orst.edu">www.npic.orst.edu</a>).</p>	



## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For manufacturing use only. For formulation into insecticides, miticides, fungicides, and nematocides, for the following general use patterns: Terrestrial food crop and nonfood crop, greenhouse food crop and nonfood crop, residential outdoor/indoor.

This product may be used to formulate products for any additional use(s) not listed on this label if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### CAUTION

Harmful if absorbed through skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

## ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in a cool, dry area. Always store pesticides in the original container. Store away from food and pet food. Do not refrigerate.

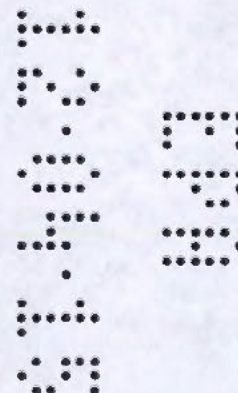
**Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused <sup>1</sup> dispose of in the same manner. Do not burn unless allowed by state and local ordinances.



## WARRANTY STATEMENT

AGRO LOGISTIC SYSTEMS, INC. warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with the directions under normal use conditions. To the extent permitted by law, AGRO LOGISTIC SYSTEMS, INC. disclaims any liability for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. It is the manufacture's intention that the buyer assumes risk of use, storage, or handling of this material not in strict accordance with directions given herein. To the extent consistent with applicable law, Agro Logistic Systems, Inc. makes no warranties of merchantability or fitness for a particular purpose nor any other express or implied warranty except as stated above.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

**RE: Notification of Non-compliance with Pesticide Registration Notice 11-3**

Email Sent Date: 07/27/15  
Email: [acadiaregulatory@gmail.com](mailto:acadiaregulatory@gmail.com)

Dear Mr. Fournier,

The Biopesticides and Pollution Prevention Division (BPPD) have received your submission dated 7/6/15 to Agency regarding the subject product, Debug Aza MUP (EPA File Symbol 70310-A). All or some of the data were rejected by our Document Processing Unit because they were not submitted as directed in PR Notice 11-3 and should be reformatted and resubmitted to the Document Processing Unit. A copy of PR Notice 11-3 can be found at our website at: [http://www.epa.gov/PR\\_Notices/pr2011-3.pdf](http://www.epa.gov/PR_Notices/pr2011-3.pdf) should you need assistance in making the necessary changes.

If you still want to register this product, the application will be kept open for a period of 75 days to give you the opportunity to respond to this memorandum. If you find that you need more time you must request an extension for a reasonable stated period of time. Extension requests must be made immediately to me at [bryceland.andrew@epa.gov](mailto:bryceland.andrew@epa.gov).

If you do not comply with this procedure by not responding to this letter or requesting an extension of time to resubmit the information, the Agency may administratively withdraw your application from further consideration under the provisions of PR Notice 75-4 of August 27, 1975. Once this is done, you will have to submit a completely new application should you wish to pursue the registration of your product after the application has been withdrawn.

The changes and/or corrections required are outlined in the attached EPA Transmittal Letter. You must contact me by telephone at (703)305-6928 or by email at [bryceland.andrew@epa.gov](mailto:bryceland.andrew@epa.gov) and indicate that you will submit the corrected pages via facsimile to (703)308-7026. Once you have faxed the corrected pages, please follow up with an email or phone call to me indicating that you have done so.

If the changes are excessive, you may wish to courier the documents to our offices. Once all the changes have been made, your submission will be forwarded to our Document Processing Unit for PR Notice 11-3 Screening.

Should you have any additional questions regarding this matter, please feel free to call me.

Sincerely,

*Andrew Bryceland*

Biopesticides and Pollution  
Prevention Division (7511P)

Cc: Ms. Gina Burnett





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

July 21, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

AGRO LOGISTIC SYSTEMS, INC.  
555 W. LAMBERT ROAD, UNIT - N  
BREA, CA 92821

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 09-JUL-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

49669801

\* End-use product-specific product chemistry data covered by guideline series 61, 62, and 63 can be combined and submitted as a single study. If you wish to claim confidentiality for material in series 61 or 62 under FIFRA section 10(d)(1), be sure to remove it from the body of the combined study, and place it in a Confidential Attachment. Assuming a Confidential Attachment is present, the study should be arranged like this: Page 1 of x Title Page, Page 2 of x Statement of Data Confidentiality Claims (version 2), Page 3 of x The body of the study, including all non-confidential data, with cross references to the location in the Confidential Attachment x of x of each passage claimed as confidential. Page 1 of y Cover page of Confidential Attachment. 2 of y Confidential data, with a page-specific cross reference at the beginning of each passage to the location in the body of the study from y of y which it was removed.




**AGRO  
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.

Ph: 714-990-9220, Fax: (714) 990-9222 www.agrologistic.com

Linda A. Hollis, Chief  
 Biochemical Pesticides Branch  
 Biopesticides and Pollution Prevention Division (7511P)  
 EPA Office of Pesticide Programs  
 One Potomac Yard  
 2777 South Crystal Drive  
 Arlington, VA 22202

July 6, 2015

RE: **Debug Aza MUP, EPA File Symbol 70310-A, Decision Number 502429**  
**Debug Tres, EPA File Symbol 70310-T, Decision Number 502467**  
**Debug Optimo, EPA File Symbol 70310-I, Decision Number 502469**  
**Response to Deficiencies from your letters dated June 29, 2015**

Dear Ms. Hollis:

Thank you for your letters dated June 29, 2015 in which you identified deficiencies and issues noted during the Preliminary 90-Day Technical Screen in the applications to register Debug Aza MUP, Debug Tres, and Debug Optimo. The following response to the noted deficiencies has been provided by the manufacturer of these products, Agro Logistic Systems:

Debug Aza MUP (70310-A) deficiencies:

1. There is a discrepancy regarding the active ingredient (AI) contained in your product.

Response: This discrepancy has been corrected – the active ingredient is now described consistently throughout the product label, CSF, manufacturing schematic, and product chemistry volumes.

2. The manufacturing process flow chart on page 9 of MRID 49586703 shown [REDACTED]

Response: The description of the manufacturing process has been revised to clarify that the [REDACTED]

3. MRID 49586701, page six, states that the only impurity in the final compound is [REDACTED]

[REDACTED] However, the CSF lists the impurities as [REDACTED]

Additionally, page five of MRID 49586701 also lists [REDACTED] the impurities in the final product.

Response: The product chemistry volume has been revised to clarify which impurities are present in the final manufacturing use product. The product contains no [REDACTED] that is now described in the narrative describing the manufacturing process as well as listed as a distinct manufacturing step on the manufacturing schematic. The

**Debug** TURBO





**AGRO  
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.

Ph: 714-990-9220, Fax: (714) 990-9222 www.agrologistic.com

only impurities in the final product are

[REDACTED] These specific impurities, their respective CAS numbers, and their percentage in formulation have all been listed on the CSF for the product and are also discussed in the narrative portion of the product chemistry volume discussing the formation of impurities.

Debug Tres (70310-T) deficiencies:

1. This product contains EPA File Symbol: 70310-A as a source of active ingredient. The Agency has identified significant deficiencies pertaining to the manufacturing process and discussion of formation of impurities for EPA File Symbol: 70310-A.

Response: The deficiencies and issues noted in your review of Debug Aza MUP (File Symbol 70310-A) have been corrected and/or clarified and the product chemistry volume for File Symbol 70310-T has also been reviewed and edited for consistency with the revisions to 70310-A.

Debug Optimo (70310-I) deficiencies:

1. This product contains EPA File Symbol: 70310-A as a source of active ingredient. The Agency has identified significant deficiencies pertaining to the manufacturing process and discussion of formation of impurities for EPA File Symbol: 70310-A.

Response: The deficiencies and issues noted in your review of Debug Aza MUP (File Symbol 70310-A) have been corrected and/or clarified and the product chemistry volume for File Symbol 70310-I has also been reviewed and edited for consistency with the revisions to 70310-A.

Many thanks to you and your staff for your attention to these product applications. We are hopeful that the responses and revised documents in this submission will sufficiently address all of the issues and deficiencies identified in your 90-day Technical Screen. If any further corrections or clarifications are needed, please contact John Fournier at (607) 220-4860 or [AcadiaRegulatory@gmail.com](mailto:AcadiaRegulatory@gmail.com).

Respectfully,

Shyam Chari



## TRANSMITTAL DOCUMENT

Date: 07/06/15

Company:

AGRO LOGISTIC SYSTEMS, INC.  
555 W. LAMBERT ROAD, UNIT N  
BREA, CA 92821  
714-990-9220

Product Name/EPA Reg. #: Debug Aza MUP (EPA Reg Number: 70310-A)

<u>MRID</u>	<u>Study No.</u>	<u>Study Title</u>
49669801	1	Group A Product Chemistry for Debug Aza MUP

**CONFIDENTIAL ATTACHMENT: CONTAINS CONFIDENTIAL BUSINESS INFORMATION**

**STUDY TITLE**

Group A Product Chemistry for Debug Aza MUP

**DATA REQUIREMENTS**

Product Identity and Composition: OPPTS 880.1100

Description of Starting materials, Production and Formulation Process: OPPTS 880.1200

Discussion of Formation of Impurities: OPPTS 880.1400

Preliminary Analysis: OPPTS 830.1700

**PERFORMING FACILITY**

Agro Logistics Systems Inc.

P.O. Box 5799

Diamond Bar, CA 91765

**PROJECT IDENTIFICATION**

AGRO LOGISTIC 15-05

**DATE**

July 6, 2015

**Volume 2 of 2**



\*Pages 44-49 Manufacturing process information may be entitled to confidential treatment\*

\*Quality control process information may be entitled to confidential treatment\*

\*Inert ingredient information may be entitled to confidential treatment\*

**APPENDIX 1: CONFIDENTIAL STATEMENT OF FORMULA**





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

**CERTIFIED MAIL**

June 29, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Mr. John Fournier  
Acadia Regulatory Consulting  
Authorized Agent for Agro Logistic Systems, Inc.  
331 West King Road  
Ithaca, NY 14850

RE: Deficiencies and Issues Noted During Preliminary 90-Day Technical Screen  
Product name: DEBUG AZA MUP  
Active Ingredient: Azadirachtin  
EPA File Symbol: 70310-A  
Decision Number: 502429  
PRIA Category: B673

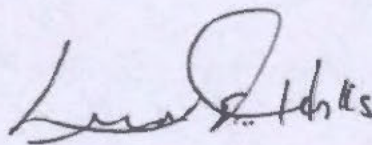
Dear Mr. Fournier:

The Agency has completed its preliminary technical screening of your application pursuant to Section 33(f)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide (FIFRA) Act, as amended by the Pesticide Registration Improvement Extension Act. The Agency has determined that your application has not passed the preliminary technical screen and therefore is subject to rejection if the application is not corrected. The deficiencies are outlined in the attached confidential appendix.

In order for the review of your product to continue, you will need to correct your application to address the item(s) listed above within 10 business days of the date you received this letter. Corrections must be received by EPA by the 10<sup>th</sup> business day. EPA recommends sending your complete set of corrections by email to the contact listed below to ensure they are timely received. If studies or confidential information are being submitted by mail, a complete courtesy copy received by email by the deadline will be considered timely. If you cannot correct the application, or do not respond within 10 business days, your application will be rejected. At this time you could also choose to withdraw your application.

The Agency wants to work with you to help move your application into the next phase of the regulatory process. As Gina Burnett, Regulatory Action Leader, Biochemical Pesticides Branch, discussed with you in a telephone conversation on June 29, 2015, we hope that the deficiencies can be addressed as outlined in the confidential appendix within the given timeframe. If you have additional questions or would like to arrange a meeting or teleconference, please contact Ms. Gina Burnett at [burnett.gina@epa.gov](mailto:burnett.gina@epa.gov), or via phone at (703) 605-0513.

Sincerely,

A handwritten signature in dark ink, appearing to read "Linda A. Hollis". The signature is fluid and cursive, with the first name "Linda" being more prominent than the last name "Hollis".

Linda A. Hollis, Chief  
Biochemical  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs



## CONFIDENTIAL APPENDIX

### Deficiencies Noted During the Technical Screen

EPA File Symbol: 70310-A

Decision No.: 502429

*Manufacturing-use Product (MP)*

Deficiency	Data/Information Submitted	Reason for Inadequacy	What Data/Information are Needed
830.1620 description of production process	49586701 49586702 49586703		
880.1200 description of starting materials, production and formulation process	49586703		

\*Manufacturing process information may be entitled to confidential treatment\*

880.1400 discussion  
of formulation of  
impurities

49586701

**Note: At this time, your Human Health Toxicity rationales submitted with this application have past the technical screen. However, in the event that significant information changes regarding your active ingredient, these rationales may be deemed unacceptable.**

\*Manufacturing process information may be entitled to confidential treatment\*



## Biochemical Pesticide Technical Screen

**Date of Tech Screen Completion:**

**PASS or FAIL:** **FAIL**

*(TO BE COMPLETED BY THE RAL):*

RAL and Reviewer	Gina Burnett/Shenell Bolden
File Symbol/Registration/Petition No.	70310-A
PRIA Code	B673
Submission No.	965504
Decision No.	502429

		<u>Label</u>		
Item:	Description:	Yes	No	N/A
a.	Restricted Use Pesticide statement (If applicable)			X
b.	Product name, brand or trademark	X		
c.	Ingredient statement correct? Microbial: strain designation Microbial: potency designation	X		
d.	"Keep Out of Reach of Children" (KOOROC) Statement	X		
e.	Signal word	X		
f.	First aid statement	X		
g.	Net contents/net weight	X		
h.	EPA Reg. No. and Establishment No.	X		
i.	Company name and address	X		
j.	Precautionary statement: hazards to human and domestic animals Microbial: dusk mask statement	X		
k.	Environmental hazards	X		
l.	Physical and chemical hazards (if app.)			X
m.	Directions for use	X		
m.	Storage and disposal	X		
o.	Warranty statement	X		
p.	Worker protection			X
q.	Batch code		X	

**RAL Comments:**

*Label needs a batch code placeholder.*

(TO BE COMPLETED BY THE REVIEWER):

Notes to reviewer: 1) when listing/discussing a specific data requirement, please also list the corresponding guideline number and 2) include the appropriate MRID number when discussing a deficiency, data, etc.

Confidential Statement of Formula (CSF)				
Item:	Description:	Yes	No	N/A
a.	Concurrence with Inerts Branch assessment of inert ingredient approval on CSF?			None to review
b.	CSF accurately reflects label	x		
c.	Active(s) + Inert(s) = 100%	x		
d.	Chemical names and CAS #s provided for inerts			None given
e.	Units in all applicable boxes	x		
f.	Supplier information adequately listed	x		
g.	Certified limits correct?	x		
h.	If certified limits are outside recommended range, explanation provided?			x
i.	If there are alternate formulations, are they actually alternate and not a new product?			x
Summary of deficiencies/Comments:				

Data Matrix-TGAI (delete table if a.i. source is registered)				
Item:	Description:	Yes	No	N/A
a.	Are all product chemistry data requirements listed?		x	
b.	Are all mammalian toxicology data requirements listed?		x	
c.	Are all nontarget organism data requirements listed?		x	
Summary of deficiencies/Comments:				
1. CSF is unclear				
1a. 25% A.I. (Azadirachtin), 75% impurities [REDACTED] What is the breakdown of the impurities and their concentrations?				
1b. Impurities are listed on CSF as "carrier." Impurities cannot be listed as carriers.				

\*Manufacturing process information may be entitled to confidential treatment\*



1c. The CSF and manufacturing process (MRID 49586703) are unclear as to the identity of the product. The product identity and composition must be more clearly described.

2. Manufacturing process is unclear (MRID 49586703). The flow chart on page nine included in the manufacturing process shows [REDACTED]

3. MRID 49586701 – Discussion of Formation of Impurities: Page six states that the only impurity in the final compound is left over [REDACTED]. However, the CSF list the impurities as [REDACTED]. Additionally, page five of the same MRID also lists [REDACTED] as the impurities in the final product.

**\*\*Note to RAL – 5 batch, storage stability and other required physical chemistry data were submitted within the administrative materials packet. Therefore, no MRID numbers were assigned to these data.**

**Data Matrix-MP or EP**

Item:	Description:	Yes	No	N/A
a.	Are all product chemistry data requirements listed?		X	
b.	Are all mammalian toxicology data requirements listed?	x		
c.	Are all nontarget organism data requirements listed?		X	
d.	Are all efficacy data listed?		x	
e.	If the a.i. is from a registered source, is the source registered for the EP's or MP's use pattern?	x		

**Summary of deficiencies/Comments:**

- a. manufacturing process does not clearly identify EP ingredients
- b. rationale submitted (MRID 49586703)
- c. no non-target data was provided with the application
- d. no efficacy data was provided with the application
- e. registered source is azadirachtin cas no. 11141-17-6

Data Requirements-TGAI (delete table if a.i. source is registered)				
Item:	Description:	Yes	No	N/A
a.	Are all product chemistry data adequate for secondary review?		X	
b.	Are all mammalian toxicology data adequate for secondary review?	x		
c.	Are all nontarget organism data adequate for secondary review?		x	
<b>Comments:</b> Deficiencies associated with the TGAI are discussed in the Deficiency Table below. c. no non-target organism data were submitted with this package.				

Deficiency Table for the unregistered source of list a.i. (delete table if a.i. source is registered)

Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information are Needed
List data requirement and guideline no.	List MRID No. and whether data, rationale, or waiver request were submitted.		
830.1620 description of production process	49586701 49586702 49586703		
880.1200 description of starting materials, production and formulation process	49586703		

\*Manufacturing process information may be entitled to confidential treatment\*



880.1400 discussion of formulation of impurities	49586701	
---	----------	--

Data Requirements-MP or EP				
Item:	Description:	Yes	No	N/A
a.	Are all product chemistry data adequate for secondary review?		x	
b.	Are all mammalian toxicology data adequate for secondary review?	x		
c.	Are all nontarget organism data adequate for secondary review?		x	
<b>Comments:</b> Non-target organism data was not submitted with this package.				

Deficiency Table for EPA Reg. No./File Symbol No.:

Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information are Needed
List data requirement and guideline no.	List MRID No. and whether data, rationale, or waiver request were submitted.		

Tolerance/Exemption/Nonfood Determination (delete if nonfood-use or already approved for food use)
--







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 19, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

AGRO LOGISTIC SYSTEMS INC  
PO.BOX : 5799  
DIAMOND BAR, CA 91765

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 12-MAR-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



**Receipt for Section 3**

S: 965504
Milestone Email:

Regulatory Type: Product Registration - Section 3
Resubmission: ☐ Yes ☒ No

Application Type: New Registration
Fee For Service: ☒ Yes ☐ No

Company: 70310 AGRO LOGISTIC SYSTEMS INC
Billable: ☒ Yes ☐ No

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 70310-A
Product Name: DEBUG AZA MUP

Override#:

Me Too Section3:
Me Too Product Name:

Application Date: 06-Mar-2015
OPP Rec'd Date: 12-Mar-2015

Front End Date: 13-Mar-2015
Risk Manager Send Date:

FFS Due Date:
Negotiated Due Date:

OPP Target Date:

Fast Track: ☐
New Ingredient: ☐

Receipt Description:
NEW REGISTRATION WITH STUDIES

Form A: ☐
Signature Date:
Form B: ☐
Signature Date:

Print Letter
Enter More Information
Tracking

Receipt Content
Study
CSF
View/Edit

Dec No 502429





**AGRO  
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.  
Ph: 714-990-9220, Fax: (714) 990-9222 www.agrologistic.com

 **ORIGINAL**

Shyam K. Chari, President  
Agro Logistic Systems, Inc.  
P.O. Box 5799  
Diamond Bar, CA 91765  
Tel. (714) 990-9220; email: [shyam@agrologistic.com](mailto:shyam@agrologistic.com)

**49586700**

Linda Hollis, Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs, EPA  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

March 6, 2015

RE: **Application for New Product Registrations**  
**File Symbol 70310-A: Debug Aza MUP, PRIA Category B673**  
**File Symbol 70310-T: Debug Optimo, PRIA Category B670**  
**File Symbol 70310-I: Debug Tres, PRIA Category B670**

Dear Ms. Hollis:

Agro Logistic Systems, Inc. (EPA Co. No. 70310), hereby submits three applications for new product registration. The first application is for a manufacturing use product, Debug Aza MUP (File Symbol 70310-A). The other two applications are for new end-use products, Debug Optimo (File Symbol 70310-T) and Debug Tres (File Symbol 70310-I).

This application fits under PRIA Category B673 for the registration of the MUP (new MUP, unregistered source of active ingredient, citation of TGAI data previously reviewed and accepted by the Agency) and B670 for the two new end use products with registered sources of active ingredients. A small business 75% waiver of the required PRIA fees is requested, and appropriate documentation is included. Enclosed you will find the following in support of each of the three applications:

- 1) Application form;
- 2) Online payment confirmation;
- 3) Small Business Waiver documentation;
- 4) Confidential Statement of Formula;
- 5) Certification with Respect to Citation of Data form;
- 6) Data Matrix, including a publicly releasable "blacked-out" version;
- 7) Five (5) copies of the product label;
- 8) Data Volumes 1 through 3 – refer to the Transmittal Document for a complete listing of data volume titles and corresponding OPPTS Guideline Numbers.
- 9) Shelf Life (Storage Stability) study.

**Debug** 



**AGRO  
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.

Ph: 714-990-9220, Fax: (714) 990-9222 [www.agrologistic.com](http://www.agrologistic.com)

10) 5-Batch Analysis

Please note the following with regards to this application:

- a. **Identity of the Products.** Debug Aza MUP is a new manufacturing use product. Debug Optimo and Debug Tres are new end-use fungicide and bactericide product containing registered active ingredients and formulated with minimum risk inert ingredients. Debug Tres also contains the new Debug Aza MUP.
- b. **Product Chemistry Data.** A complete set of product chemistry data for each product is submitted with these applications – refer to Volume 2 of each product submission.
- c. **Human Health Toxicity Data.** Scientifically sound data rationales have been submitted for all human health toxicity data requirements for each product – refer to Volume 3 of each submission. Data waiver rationales are based on toxicity information available on the active ingredients, inert ingredients, and their breakdown products, as well as a discussion on potential human exposure, or lack thereof.

With this application, we believe all biochemical pesticide Tier 1 data requirements for new MUP and end-use products have been fulfilled. Please contact me if there are any questions or comments.

Respectfully,

Shyam K. Chari, President  
Agro Logistic Systems, Inc.

P.O. Box 5799

Diamond Bar, CA 91765

Tel. (714) 990-9220; email: [shyam@agrologistic.com](mailto:shyam@agrologistic.com)

**Debug** TURBO



VOLUME 1 OF 3 OF SUBMISSION  
**TRANSMITTAL DOCUMENT**

**NAME AND ADDRESS OF SUBMITTER:**

Agro Logistic Systems, Inc.  
P.O. Box 5799  
Diamond Bar, CA 91765

**REGULATORY ACTION:**

PRIA B673 Application for Registration of **Debug Aza MUP**

**TRANSMITTAL DATE:**

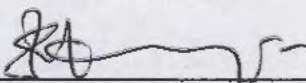
March 6, 2015

**LIST OF SUBMITTED STUDIES:**

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	OCSPP GUIDELINE NUMBER
	1 of 3	Transmittal Document, Admin Documents	-----
<b>49586701</b>	2 of 3	Product Chemistry for Debug Aza MUP	880.1100
<b>49586702</b>			880.1200
			830.1750
<b>49586703</b>	3 of 3	Response to Tier 1 Biochemical Pesticide Data Requirements for Debug Aza MUP	870.1100
			870.1200
			870.1300
			870.2400
			870.2500
			870.2600

**COMPANY NAME:** Agro Logistic Systems, Inc.

**COMPANY OFFICIAL:**

  
Shyam K. Chari, President

**COMPANY CONTACT:**

Shyam K. Chari, President  
Agro Logistic Systems, Inc.  
P.O. Box 5799  
Diamond Bar, CA 91765  
Tel. (714) 990-9220; email: [shyam@agrologistic.com](mailto:shyam@agrologistic.com)



# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 3-11-15

Experts In-Processing Signature: B.B.

Date 3-19-15

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>70310-A</u>		EPA Receipt Date: <u>3-11-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<i>Active and impurities only</i>					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	<u>Notice of Filing</u> included with <u>petitions</u>					X



9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

Documentation: Pass

- Required forms are complete.

Inerts:

- Active ingredient and impurities only,  
no inerts to review.

11-35 Pass

MRID - 495867

Status: Pass

TJ 4/11/15



\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.



During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

#### Unapproved Inerts Identified on CSFs

##### All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

##### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)



3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 18, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-502429  
EPA File Symbol or Registration Number: 70310-A  
Product Name: DEBUG AZA MUP  
EPA Receipt Date: 12-Mar-2015  
EPA Company Number: 70310  
Company Name: AGRO LOGISTIC SYSTEMS INC

SHYAM K CHARI  
AGRO LOGISTIC SYSTEMS INC  
PO Box 5799  
DIAMOND BAR, CA 91765

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B673

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT;CITATION OF TGA1 DATA PREVIOUSLY REVIEWED AND ACCEPTED BY THE AGENCY;REQUIRES AN AGENCY DETERMINATION THAT THE CITED DATA SUPPORTS THE NEW PRODUCT;REQUIRES AN AGENCY DETERMINATION THAT THE CITED DATA SUPPORTS THE NEW PRODUCT;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-0107.

Sincerely,

*Meresa Downs*  
Front End Processing Staff

Information Technology & Resources Management Division



# Fee for Service

965504\$~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 75

for Division

☐ AD

☒ BPPD

☐ RD

Risk Mgr.

91

Receipt No.

S-

965504

EPA File Symbol/Reg. No.

70310-A

Pin-Punch Date:

3/12/2015

☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

B673

Granted:

B673

Amount Due: \$ 4863

## Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Andrew Bryceland

Date: 3-18-15

Remarks:



# Receipt for Section 3

S: 965504

Milestone Wait:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Company: 70310 AGRO LOGISTIC SYSTEMS INC

V

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 70310-A Product Name: DEBUG AZA MUP

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 06-Mar-2015

OPP Rec'd Date: 12-Mar-2015

Front End Date: 13-Mar-2015

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

NEW REGISTRATION WITH STUDIES

Receipt Content

Study

CSF

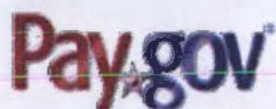
View/Edit

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

**Receipt****Your payment is complete**

Pay.gov Tracking ID: 25K5C5AD

Agency Tracking ID: 74764948386

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

**Payment Information**

Payment Type: Debit or credit card

Payment Amount: \$1,215.75

Transaction Date: 03/05/2015 03:14:09 PM EST

Payment Date: 03/05/2015

Registration Number: 70310-A

Company Name: AGRO LOGISTIC SYSTEMS INC

Company Number: 70310

Action Code: B673

**Account Information**

Card Holder Name: shyam chari

Billing Address: 2145 Indian Creek Road

Billing Address 2:

City: Diamond Bar

Country: United States

State/Province: CA

ZIP/Postal Code: 91765

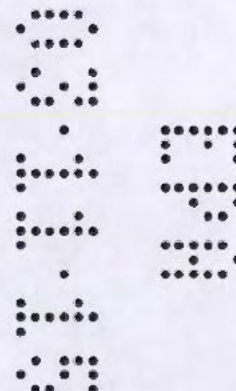
Card Type: Master Card

Card Number: \*\*\*\*\*9721

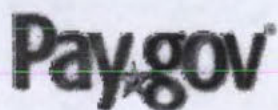
**Email Confirmation Receipt**

Confirmation Receipts have been emailed to:

shyam@agrologistic.com







## Receipt

### Your payment is complete

Pay.gov Tracking ID: 25K5C5AD

Agency Tracking ID: 74764948386

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

### Payment Information

Payment Type: Debit or credit card

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Payment Date: 03/05/2015

Registration Number: 70310-A

Company Name: AGRO LOGISTIC SYSTEMS INC

Company Number: 70310

Action Code: B673

### Account Information

Card Holder Name: shyam chari

Billing Address: 2145 Indian Creek Road

Billing Address 2:

City: Diamond Bar

Country: United States

State/Province: CA

ZIP/Postal Code: 91765

Card Type: Master Card

Card Number: \*\*\*\*\*9721

### Email Confirmation Receipt

Confirmation Receipts have been emailed to:

shyam@agrologistic.com







United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 70310/70310-A	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Agro Logistic Systems, Inc./Debug Aza MUP	PM# 91	
5. Name and Address of Applicant (Include ZIP Code) Agro Logistic Systems, Inc., P.O. Box 5799 Diamond Bar, CA 91765  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for registration of Debug Aza MUP, a new manufacturing use product under PRIA Category B673.

## Section - III

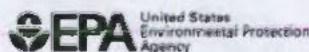
1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container bulk containers		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product glued		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Shyam K. Chari	Title President	Telephone No. (include Area Code) (714) 990-9220
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped)
2. Signature 	3. Title President	
4. Typed Name Shyam K. Chari	5. Date 6 March 2015	



## Menu



## B673 PRIA Fee Category

### PRIA 3 Fee Determination Decision Tree:

### Biochemical or Microbial Biopesticide Active Ingredient - New Product Registration

Below is the fee for your selected Fee Category for Fiscal Years 2014/2015

Action Code	Description	FY14/15 Fee	Decision Time (months)
B673	New product MUP/EP; unregistered source of active ingredient(s); citation of Technical Grade Active Ingredient (TGAI) data previously reviewed and accepted by the Agency. Requires an Agency determination that the cited data supports the new product. (2)	\$ 4,863	10

### PRIA Decision Tree

Go to the start of the Decision Tree

**Do you plan to request either of the following types of waivers?**

50% waiver You pay ---->>>>> \$ 2,432

75% waiver You pay ---->>>>> \$ 1,216

*To pay the fee shown above, go to Paying PRIA Application Fees web page and follow the instructions.*

How to submit your application directly to EPA.

### Action Code Interpretation



An application for registration of a new microbial or biochemical pesticide product (MUP or end use product) containing an unregistered source of a registered active ingredient for which the data cited to fulfill all TGAI data requirements has been previously reviewed and accepted by the Agency. If an update to the TGAI risk assessment is required, then this category does not apply. See category B672.

For microbial pesticides this category does not apply when data to demonstrate similarity is needed to bridge to previously reviewed and accepted data. See Table 11; New Active Ingredients.

All of the inerts used in the product must be either approved or pending with the Agency for the applicable uses.

An application for a new end-use product using a source of active ingredient that is not yet registered but has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of an active ingredient.

Go to the start of the Decision Tree

Last updated on November 17, 2014

VOLUME 1 OF 3 OF SUBMISSION  
**TRANSMITTAL DOCUMENT**

**NAME AND ADDRESS OF SUBMITTER:**

Agro Logistic Systems, Inc.  
P.O. Box 5799  
Diamond Bar, CA 91765

**REGULATORY ACTION:**

PRIA B670 Application for Registration of **Debug Optimo**

**TRANSMITTAL DATE:**


March 6, 2015

**LIST OF SUBMITTED STUDIES:**

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	OCSP GUIDELINE NUMBER
	1 of 3	Transmittal Document, Admin Documents	-----
	2 of 3	Product Chemistry for Debug Optimo	880.1100 880.1200 830.1750
	3 of 3	Response to Tier 1 Biochemical Pesticide Data Requirements for Debug Optimo	870.1100 870.1200 870.1300 870.2400 870.2500 870.2600

**COMPANY NAME:** Agro Logistic Systems, Inc.

**COMPANY OFFICIAL:**

  
\_\_\_\_\_  
Shyam K. Chari, President

**COMPANY CONTACT:**

Shyam K. Chari, President  
Agro Logistic Systems, Inc.  
P.O. Box 5799  
Diamond Bar, CA 91765  
Tel. (714) 990-9220; email: [shyam@agrologistic.com](mailto:shyam@agrologistic.com)





**AGRO  
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.  
Ph: 714-990-9220, Fax: (714) 990-9222 [www.agrologistic.com](http://www.agrologistic.com)

 **ORIGINAL**

Shyam K. Chari, President  
Agro Logistic Systems, Inc.  
P.O. Box 5799  
Diamond Bar, CA 91765  
Tel. (714) 990-9220; email: [shyam@agrologistic.com](mailto:shyam@agrologistic.com)

Linda Hollis, Chief, Biochemical Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs, EPA  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

March 6, 2015

RE: **Application for New Product Registrations**  
**File Symbol 70310-A: Debug Aza MUP, PRIA Category B673**  
**File Symbol 70310-T: Debug Optimo, PRIA Category B670**  
**File Symbol 70310-I: Debug Tres, PRIA Category B670**

Dear Ms. Hollis:

Agro Logistic Systems, Inc. (EPA Co. No. 70310), hereby submits three applications for new product registration. The first application is for a manufacturing use product, Debug Aza MUP (File Symbol 70310-A). The other two applications are for new end-use products, Debug Optimo (File Symbol 70310-T) and Debug Tres (File Symbol 70310-I).

This application fits under PRIA Category B673 for the registration of the MUP (new MUP, unregistered source of active ingredient, citation of TGAI data previously reviewed and accepted by the Agency) and B670 for the two new end use products with registered sources of active ingredients. A small business 75% waiver of the required PRIA fees is requested, and appropriate documentation is included. Enclosed you will find the following in support of each of the three applications:

- 1) Application form;
- 2) Online payment confirmation;
- 3) Small Business Waiver documentation;
- 4) Confidential Statement of Formula;
- 5) Certification with Respect to Citation of Data form;
- 6) Data Matrix, including a publicly releasable "blacked-out" version;
- 7) Five (5) copies of the product label;
- 8) Data Volumes 1 through 3 – refer to the Transmittal Document for a complete listing of data volume titles and corresponding OPPTS Guideline Numbers.
- 9) Shelf Life (Storage Stability) study.

**Debug** TURBO





**AGRO  
LOGISTIC SYSTEMS INC.**

555 W. Lambert Road, Unit - N, Brea, CA 92821.  
Ph: 714-990-9220, Fax: (714) 990-9222 [www.agrologistic.com](http://www.agrologistic.com)

10) 5-Batch Analysis

Please note the following with regards to this application:

- a. **Identity of the Products.** Debug Aza MUP is a new manufacturing use product. Debug Optimo and Debug Tres are new end-use fungicide and bactericide product containing registered active ingredients and formulated with minimum risk inert ingredients. Debug Tres also contains the new Debug Aza MUP.
- b. **Product Chemistry Data.** A complete set of product chemistry data for each product is submitted with these applications – refer to Volume 2 of each product submission.
- c. **Human Health Toxicity Data.** Scientifically sound data rationales have been submitted for all human health toxicity data requirements for each product – refer to Volume 3 of each submission. Data waiver rationales are based on toxicity information available on the active ingredients, inert ingredients, and their breakdown products, as well as a discussion on potential human exposure, or lack thereof.

With this application, we believe all biochemical pesticide Tier 1 data requirements for new MUP and end-use products have been fulfilled. Please contact me if there are any questions or comments.

Respectfully,

Shyam K. Chari, President  
Agro Logistic Systems, Inc.  
P.O. Box 5799  
Diamond Bar, CA 91765  
Tel. (714) 990-9220; email: [shyam@agrologistic.com](mailto:shyam@agrologistic.com)

**Debug** TURBO





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Agro Logistic Systems, Inc., P.O. Box 5799, Diamond Bar, CA 91765	EPA Registration Number/File Symbol 70310-A
Active Ingredient(s) and/or representative test compound(s) azadirachtin	Date March 6, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Manufacturing Use Product	Product Name Debug Aza MUP

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

March 6, 2015

Typed or Printed Name and Title

Shyam K. Chari, President



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W. WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date March 6, 2015

EPA Reg. No./File Symbol  
70310-A

Page 1 of 1

## Applicant's/Registrant Name and Address

Agro Logistic Systems, Inc.  
P.O. Box 5799  
Diamond Bar, CA 91765

## Product

Debug Aza MUP

Ingredient Azadirachtin

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 880.1100	Product Identity and Composition		Agro Logistic Systems, Inc.	OWN	
OPPTS 880.1200	Description of Starting Materials, Production and Formulation Processes		Agro Logistic Systems, Inc.	OWN	
OPPTS 830.1750	Certified Limits		Agro Logistic Systems, Inc.	OWN	
OPPTS 870.1100	Acute Oral Toxicity		Agro Logistic Systems, Inc.	OWN	
OPPTS 870.1200	Acute Dermal Toxicity		Agro Logistic Systems, Inc.	OWN	
OPPTS 870.1300	Acute Inhalation Toxicity		Agro Logistic Systems, Inc.	OWN	
OPPTS 870.2400	Primary Eye Irritation		Agro Logistic Systems, Inc.	OWN	
OPPTS 870.2500	Primary Dermal Irritation		Agro Logistic Systems, Inc.	OWN	
OPPTS 870.2600	Dermal Sensitization		Agro Logistic Systems, Inc.	OWN	

Signature



Name and Title

Shyam K. Chari, President

Date

March 6, 2015



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Product

Debug Aza MUP

Ingredient Azadirachtin

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OWN

Agro Logistic Systems,  
Inc.

OWN

Signature

Name and Title

Shyam K. Chari, President

Date

March 6, 2015

# Debug Aza MUP

## For Manufacturing Use Only

**Active Ingredient:**

Azadirachtin\* ..... 25.0%

**Other Ingredients**..... 75.0%

Total ..... 100.0%

- Derived from neem seeds 0.25 lbs (113 grams) of Active Ingredient per pound of product

**KEEP OUT OF REACH OF CHILDREN**

### CAUTION

See below for additional precautionary statements.

Net Contents: (10lbs, 25lbs, bulk)

EPA Reg. No. 70310-A      EPA Est. No. 70310-IND-002

**Manufactured For**

Agro Logistic Systems, Inc.

P.O. Box 5799, Diamond Bar, CA 91765, U.S.A.

Website: [www.agrologistic.com](http://www.agrologistic.com)

TEL: (714) 990-9220

FAX: (714) 990-9222 e-mail:

[info@agrologistic.com](mailto:info@agrologistic.com)

#### FIRST AID

<b>If on Skin or Clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Immediately rinse skin with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If Inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 AM to 4:30 PM Pacific Time (NPIC Web Site: [www.npic.orst.edu](http://www.npic.orst.edu)).



## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For manufacturing use only. For formulation into insecticides, miticides, fungicides, and nematicides, for the following general use patterns: Terrestrial food crop and nonfood crop, greenhouse food crop and nonfood crop, residential outdoor/indoor.

This product may be used to formulate products for any additional use(s) not listed on this label if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

### CAUTION

Harmful if absorbed through skin or inhaled. Avoid contact with skin, eyes or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

## ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store in a cool, dry area. Always store pesticides in the original container. Store away from food and pet food. Do not refrigerate.

**Pesticide Disposal:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Disposal:** Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in sanitary landfill or by incineration if allowed by State and local authorities. If drum is contaminated and cannot be reused <sup>1</sup>, dispose of in the same manner. Do not burn unless allowed by state and local ordinances.

## WARRANTY STATEMENT

AGRO LOGISTIC SYSTEMS, INC. warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for purposes stated on such label only when used in accordance with the directions under normal use conditions. To the extent permitted by law, AGRO LOGISTIC SYSTEMS, INC. disclaims any liability for consequential, special or indirect damages resulting from the use or handling of this product. All such risks shall be assumed by the Buyer. It is the manufacture's intention that the buyer assumes risk of use, storage, or handling of this material not in strict accordance with directions given herein. To the extent consistent with applicable law, Agro Logistic Systems, Inc. makes no warranties of merchantability or fitness for a particular purpose nor any other express or implied warranty except as stated above.



# Debug Aza MUP

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**Other Ingredients**..... 75.0%

Total..... 100.0%

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**401 M Street, S.W. WASHINGTON, D.C. 20460**

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**DATA MATRIX**


Date July 6, 2015		EPA Reg. No./File Symbol 70310-A		Page 1 of 1	
Applicant's/Registrant Name and Address Agro Logistic Systems, Inc. P.O. Box 5799 Diamond Bar, CA 91765			Product  Debug Aza MUP		
Ingredient Azadirachtin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Signature 			Name and Title Shyam K. Chari, President		Date July 6, 2015



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Signature 			Name and Title Shyam K. Chari, President		Date July 6, 2015